K080253

8. SUMMARY OF SAFETY & EFFECTIVENESS

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This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	Kimberly-Clark* 1400 Holcomb Bridge Road Roswell, GA 30076
OFFICIAL CORRESPONDENT	Sherry Saurini Associate Director, Regulatory Affairs Tel: 770.587.8502 Fax: 920.969.3455 email: sherry.saurini@kcc.com
TRADE NAME:	KIMBERLY-CLARK* Introducer Kits
CLASSIFICATION NAME:	Gastrointestinal tube and accessories
DEVICE CLASSIFICATION AND PRODUCT CODE	Class II per 21 CFR §876.5980 Product Code - KNT

FEB 26 2008

SUBSTANTIAL EQUIVALENCE:

The new Kimberly-Clark* Introducer Kits are substantially equivalent to the MIC* Gastrostomy Tube Percutaneous Insertion Kit cleared under K852363, the MIC* Gastro-Enterostomy Tube Modification cleared under K921370 and the MIC* Transgastric Jejunal Tube Kit cleared under K926581. Both the Kimberly-Clark* Introducer Kits and the predicate kit have the same intended use and basic scientific technology.

Both kits have the same intended use, and utilize the same scientific principles, dilation and attachment of the gastric wall to the anterior abdominal wall. Bench testing has demonstrated that the new Kimberly-Clark* Introducer Kits performs the same function as the predicate kits, and that any minor differences between the modified device and the predicate device do not affect safety or efficacy.

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DESCRIPTION OF THE DEVICE:

The Introducer Kits consists of a group of essential components required to facilitate placement of a balloon-retained enteral feeding tube. The kit contains these essential components in an easy to use tray and is configured for use in an interventional radiology and /or endoscopy suite.

This device consists of the following components and accessories:

1. Gastropexy
2. Dilator with Peel-away sheath
3. Syringe
4. Hemostat
5. Introducer Needle
6. Seeking Catheter
7. Scalpel
8. Guidewire
9. Stoma Measuring Device

The device consists of the following main components and accessories: list components and accessories.

INDICATIONS FOR USE:

Kit Configuration	Indications for Use Statement
For the Kimberly-Clark* MIC*G Introducer Kit	The Kimberly-Clark* MIC* G Introducer Kits are intended to facilitate primary placement of Kimberly-Clark* and Kimberly-Clark* MIC* brand of Gastrostomy Feeding Tubes.
For the Kimberly-Clark* MIC-KEY*G Introducer Kit	The Kimberly-Clark* MIC-KEY* G Introducer Kits are intended to facilitate primary placement of Kimberly-Clark* and Kimberly-Clark* MIC-KEY* brand of Gastrostomy Feeding Tubes.
For the Kimberly-Clark* MIC*J-TJ Introducer Kit	The Kimberly-Clark* MIC* Jejunal and Kimberly-Clark* MIC* Transgastric-Jejunal Introducer Kit is intended to facilitate primary placement of Kimberly-Clark* MIC* Jejunal Feeding Tube and the Kimberly-Clark* MIC* Transgastric-Jejunal Feeding Tube.
For the Kimberly-Clark* MIC-KEY*J-TJ Introducer Kit	The Kimberly-Clark* MIC-KEY* Jejunal and Kimberly-Clark* MIC-KEY* Transgastric-Jejunal Introducer Kit is intended to facilitate primary placement of Kimberly-Clark* MIC-KEY* Low-Profile Jejunal Feeding Tube and the Kimberly-Clark* MIC-KEY* Low-Profile Transgastric-Jejunal Feeding Tube.

PERFORMANCE DATA:

All components that come in direct contact with the patient have a history of use in medical devices and are biocompatible. Biocompatibility, sterilization and functional test results demonstrate that the device is safe and effective for use in humans. Biocompatibility summaries can be found in Attachment D.

CONCLUSION:

Based on the performance testing, it can be concluded that the new Kimberly-Clark* Introducer Kits are equivalent to the predicates MIC* Gastrostomy Tube Percutaneous Insertion Kit (K852363), MIC* Enterostomy Tube Modification (K921370) and MIC* Transgastric Jejunal Tube Kit (K926581) with respect to intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 2008

Ms. Sherry Saurini
Associate Director, Regulatory Affairs
Kimberly-Clark* Corporation
1400 Holcomb Bridge Road
ROSWELL GA 30076

Re: K080253
Trade/Device Name: Kimberly-Clark* MIC* G, MIC-KEY* G, MIC* Jejunal, MIC* Transgastric-Jejunal, MIC-KEY* Jejunal and MIC-KEY* Transgastric-Jejunal Introducer Kits
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KGC
Dated: January 30, 2008
Received: January 31, 2008

Dear Ms. Saurini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh.dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Indications for Use

510(k) Number (if known): K080253

Device Name: Kimberly-Clark* Introducer Kits

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Prescription Use X (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080253